

**Amendments to the Drawings:**

There are no amendments to the drawings.

**REMARKS/ARGUMENTS**

Claims pending in this application are Claims 1-3 and 6-7. Claims 4 and 5 are withdrawn without prejudice. Applicants reserve the right to pursue subject matter of non-elected species in a co-pending and/or later filed continuation or divisional applications. Accordingly, Claims 1-3 and 6-7 will be before the Examiner for consideration.

**35 U.S.C. § 102(b) Rejection**

1. The Examiner had rejected Claims 1-3 and 6-7 under 35 U.S.C. §102(b) as being unpatentable over the Struszczyk, et al (WO 91/00298 hereinafter referred to as, "the Struszczyk publication). The Examiner states that Claim 1-3 and 6 anticipate the instantly claimed method of deproteinizing chitosan in view of the use of analogous chitosan starting material, the acetic acid and sodium hydroxide as the reactants, and ultrafiltration as the purifying method. The Examiner further states that Claim 7 is rejected under 102(b) as also being anticipates by the Struszczyk publication because the office considers product-by-process claims as product claims and that the process limitations of this claims have not been considered since process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. Applicants respectfully traverse both rejections.

Applicants believe that Claims 1-3 and 6 do not anticipate the Struszczyk publication because experiments described in Applicants invention prove that the methods in Struszczyk publication do not produce a microcrystalline chitosan having a protein content less than 10 ppm. Examiner is directed to Example III of the disclosure of International Publication number WO 03/066682, page 4, lines 24-37. This part of the experiment is similar to the methods utilized in the Struszczyk publication. However, after this continuous step was completed the polymer is 0.5 – 10.0 wt% but the protein content is still higher that 10 ppm, and a further 2 step process was need to remove the protein content to be less than 10 ppm. Further experimentation was needed to remove the protein content to less than 100 ppm. Examiner is further directed to the passage on page 4, lines 37-46 where Applicants found through experimentation that additional steps

were needed which included taking the resultant products of the Struszczyk publication methods and further requiring an additional non-continuous step of adding a first aqueous basic solution to reach  $6.0 \leq \text{pH} \leq 6.5$  and then adding a second aqueous basic solution, wherein the concentration ratio of alkali in said first aqueous basic solution to said second aqueous basic solution is between 1:0.1 to 1:0.9.

As a result, the Struszczyk publication does not teach removing the protein content of chitosan to less than 10 ppm and that Applicants further non-continuous steps is required to achieve this result. Applicants have amended Claim 1 to incorporate the limitation of Claims 4 and 5, which were not a basis of Examiner's rejection. Applicants respectfully request reconsideration and withdraw the rejection to Claims 1-3 of Applicants invention.

Examiner further rejects Claim 7 as being rejected based on the sole fact that it there is a rejected on the process claims not being patentably distinguished over the prior art. Applicants believe that newly amended Claim 1 incorporating limitations not taught in the Struszczyk publication is now patentably distinct, that Claim 7 should now be considered. Applicants respectfully request that Claim 7 be reconsidered and withdrawn in light of newly amended Claim 1.

#### 35 U.S.C. § 103(a) Rejection

2. The Examiner had rejected Claims 1-3 and 6 under 35 U.S.C. §103(a) as being unpatentable over the Struszczyk publication. Examiner states that Applicants claims differ than the Struszczyk publication by claiming the reaction of the method at  $6.0 \leq \text{pH} \leq 6.5$ . Also that it is within the skill of a practitioner in this art to make adjustments to this method in order to obtained optimum operation of the claimed method. That the limitation of a process wit respect to ranges of pH, time, and temperature does not impart patentability to process when such values are those, which would be determined by one skilled in the art in achieving optimum operation of the process. Furthermore, that one of ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous materials to react similarly and that adjusting the pH value

of the reaction medium in the method of manufacturing the microcrystalline chitosan for optimum operation of the method in view of similar used reactants used to carry out the methods and the resulting expectation of similar microcrystalline chitosan properties. Applicants respectfully traverse.

Applicants are not just simply changing the pH in the method described in the Struszczyk publication to remove the protein content to be less than 10 ppm. Instead, as described above, Applicants found through experimentation that AFTER the method described in the Struszczyk publication was performed that the polymer content was 0.5 – 10.0 wt% but the protein content is still higher than 10 ppm and that additional steps were further required which was additional non-continuous steps of adding a first aqueous basic solution to reach  $6.0 \leq \text{pH} \leq 6.5$  and then adding a second aqueous basic solution, wherein the concentration ratio of alkali in said first aqueous basic solution to said second aqueous basic solution is between 1:0.1 to 1:0.9. Claim 1 has been amended to incorporate the limitations of Claims 4 and 5. In light of the newly amended Claim 1, the Struszczyk publication does not teach or suggest a method of obtaining a chitosan having a protein content of less than 10 ppm, nor does the publication teach the use of a reaction in the range of  $6.0 \leq \text{pH} \leq 6.5$ , nor does the publication teach non-continuous reacting steps of a first and second basic solutions.

Furthermore, the motivation in the present invention is to have chitosan with a protein content less than 10 ppm because proteins cause adverse reactions in humans. As a result the less protein content is necessary for acceptable pharmaceutical and medical uses which is described in Examples III-VI. This problem is not taught or suggested in the Struszczyk publication.

In light of newly amended Claim 1, Applicants respectfully request reconsideration of Claims 1-6 and withdraw the grounds of the rejection and allowance of these Claims.

Applicants submit that all grounds for rejection of claims presented herein have been addressed. Accordingly, Claims 1-3 and 6-7 will be before the Examiner for prosecution on the merits.

The Commissioner is authorized to charge any fees associated with filing of this response to Deposit Account No. 01-0025.

Applicants invite the Examiner to call the undersigned if clarification is needed on any aspect of this response, or if the examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully Submitted,

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Abbott Laboratories

D377/APA6A-1

100 Abbott Park Road

Abbott Park, IL 60064-6008

Telephone: (650) 474-3447

Facsimile: (847) 938-2623

A handwritten signature in black ink, appearing to read 'Ch. Haley', written over a horizontal line.

CHARLENE A. HALEY

Attorney for Applicants

Registration No. 52,983